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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: October 11th, 2006

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SUBJECT: Aldicarb: Acute Dietary Exposure Assessment to Support the Reregistration Eligibility Decision
PC Code: 098301

FROM: Steven M. Nako, Statistician
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~~I. Introduction~~~~Scope, Purpose, and Overview:~~

The Special Review and Reregistration Division (SRRD) ~~asked~~requested that HED ~~to~~ assess dietary risks to aldicarb to support its Reregistration Eligibility Decision. The acute adverse effect of cholinesterase inhibition tends to reverse itself ~~in the~~within hours following exposure to aldicarb. The available toxicological data indicates that aldicarb has an estimated half-life for RBC cholinesterase inhibition of two~~2~~ hours.~~(wording)~~based on data from rats and human subjects. Since the food diaries used by Dietary Exposure Evaluation Model-Food Consumption Intake Database (DEEM-FCID Version 2.03) are based on total daily intake, the estimated risks produced by this software will overestimate risks to the extent that foods and drinking water are consumed throughout the day, rather than during only one event. To ~~account for potential~~

~~reversibility in toxicological effects~~provide a better approximation of the potential exposure leading to peak RBC ChE inhibition, ~~we~~ potential exposure from food and/or water to aldicarb was~~computed the exposures and cumulative risks~~ computed ~~incrementally~~ throughout the day. This computation was made by -incorporat~~eding~~ ~~the~~ time of day and amounts consumed ~~for each consumption eating~~ during each occasion from the USDA CSFII food diaries. The potential for accumulation of toxicity was accounted for by computing the degree to which exposures could be discounted between exposure occasions, assuming a two-hour half-life. ~~to estimate exposures and risks on each eating occasion throughout the day.~~

This document is divided into five sections. Section I introduces issues associated with the kinetics of aldicarb and recovery of AChE inhibition.
Section II discusses the dietary inputs used in the modeling and covers the anticipated residues in food and predicted drinking water concentrations used in the assessment ~~highlights the approach and method for calculating exposures by eating occasion using~~ the DEEM model ~~to do what?~~. ~~To verify these DEEM-based eating occasion results, the Agency's Office of Research and Development's Stochastic Human Exposure and Dose Simulation (SHEDS) model was also used to conduct an eating occasion analyses for aldicarb. The SHEDS baseline analysis summing exposure 24 hours and the results of the eating occasion results analysis are similar to the DEEM-based results, providing additional assurance regarding the accuracy of these computations. SHEDS was also used to conduct further sensitivity analyses on the half-life parameter, as well as addressingevaluate issues regarding both direct and indirect drinking water consumption.~~ ~~This memo summarizes these aldicarb dietary exposure analyses using these two models.~~

Section III highlights the approach and method for calculating exposures ~~on an~~ by eating ~~drinking~~ occasion ~~basis~~ supplemented by analyses using SAS to do what? and SHEDS. SHEDS was also used to further explore issues associated with both direct and indirect drinking water consumption [note from DJM: **explain~~exactly~~** what issues**?**]. Section IV summarizes some exploratory analyses of drinking water consumption patterns. Bayer CropScience sponsored a Drinking Water Consumption Survey (DWCS), collecting 7 day diaries from over 4,000 participants. These data were used to conduct an alternative dietary exposure analyses, in which these DWCS diaries were used to empirically allocate direct drinking water consumption throughout the day. Finally, ~~Using the DWCS data, the risks at the per capita 99.9th percentile are very similar to those estimated using six equal and fixed events.~~ Section V provides a brief summary of our conclusions and a risk characterization.

~~Table 1 presents~~ summarize~~s~~ ~~the respective~~the results of the DEEM and SHEDS' analyses ~~estimated risks at the per capita 99.9th percentile~~ for the eating occasion analysis using a two? hour half-life for aldicarb. ~~These results are presented as % of the acute Population Adjusted Dose (aPAD). This aPAD was derived from a BMDL10 of XXX from human subjects and a 20X total uncertainty factor: [10X for intraspecies extrapolation (ie. within the human population) and 2X FQPA safety factor to account for increased sensitivity of infants and children].~~ ~~For food only, these levels are below the level of concern for all subpopulations. Four drinking water concentration scenarios were modeled for aldicarb: 3 ground water scenarios for aldicarb use on peanuts/cotton in Georgia with an assumption of 300 ft, 500 ft and 1000 ft well~~

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~~set backs, and one ground water scenario for aldicarb use on Florida citrus with a 1000 ft set back. The estimated risks at the per capita 99.9th percentile are below the level of concern for all four scenarios, for all subpopulations except for infants. For infants, the estimated risks at the per capita 99.9th percentile exceeds the level of concern under the Georgia 300 ft scenario (139% – 147% of the aPAD). As Figure 1 illustrates, the estimated risks is at 100% of the aPAD at approximately the per capita 99.7 percentile of the infant subpopulation.~~

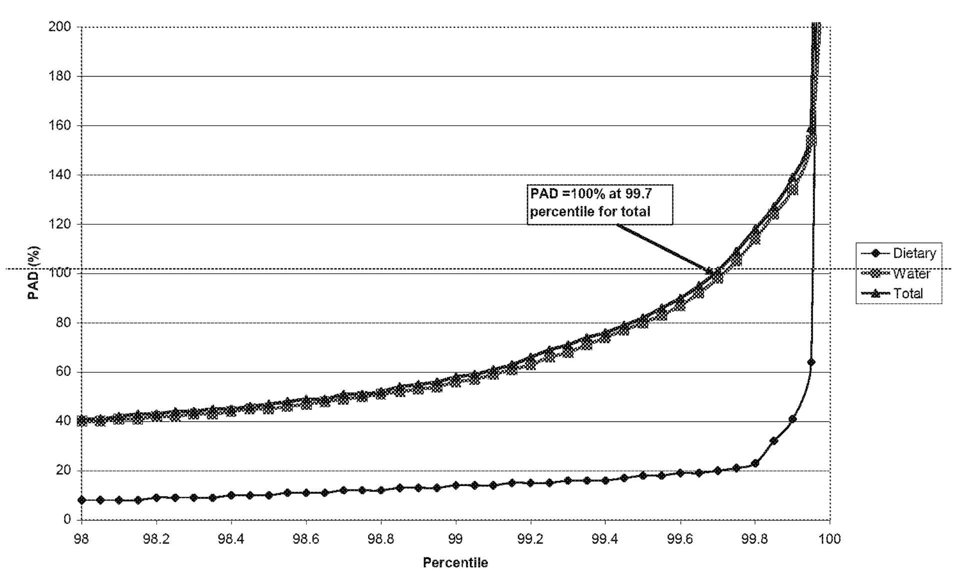
~~**Table 1. Estimated Risks at the Per Capita 99.9th (2 hr half-life)**~~

Subpopulation	DEEM-Based Eating Occasion				
	Food Only	GA-GW 300 ft	GA-GW 500 ft	GA-GW 1000 ft	FL-SW 1000 ft
USPop	34%	53%	44%	36%	42%
All Infants	41%	147%	88%	43%	80%
Children 1-2 yrs	72%	95%	80%	76%	78%
Children 3-5 yrs	60%	77%	64%	59%	62%
Children 6-12 yrs	46%	48%	45%	42%	44%
Youth 13-19 yrs	28%	46%	33%	28%	30%
Adults 20-49 yrs	29%	54%	38%	30%	36%
Adults 50+ yrs	34%	47%	37%	34%	37%
Females 13-49 yrs	29%	56%	35%	28%	34%
Subpopulation	**SHEDS-NMC Eating Occasion**				
	Food Only	GA-GW 300 ft	GA-GW 500 ft	GA-GW 1000 ft	FL-SW 1000 ft
USPop	35%	55%	42%	36%	41%
All Infants	41%	139%	85%	42%	77%
Children 1-2 yrs	77%	91%	80%	78%	79%
Children 3-5 yrs	57%	71%	61%	57%	60%
Children 6-12 yrs	43%	46%	44%	43%	44%
Youth 13-19 yrs	31%	44%	34%	31%	33%
Adults 20-49 yrs	30%	52%	37%	30%	36%
Adults 50+ yrs	32%	45%	36%	33%	35%
Females 13-49 yrs	30%	50%	37%	30%	36%

~~These eating occasion results are based on several major assumptions: (i) 2 hour half-life, (ii) allocation of direct drinking water consumption based on six6 equal and fixed occasions, and (iii) no modifications to the amount of indirect drinking water consumed as reported in the CSFII diaries for infants. Section II presents the anticipated residues (food) and predicted drinking water concentrations used in this analyses. Section III highlights the approach and method for calculating exposures, by eating occasion. We present some preliminary sensitivity analyses that were performed on the half-life parameter to assess how robust the estimated risks were to this parameter. We found that the risks at the 99.9th percentile does not change significantly when the half-life is increased from 2 hours to 3 hours. Section IV summarizes some exploratory analyses of drinking water consumption patterns. Bayer CropScience sponsored a Drinking Water Consumption Survey (DWCS), collecting 7 day diaries from over 4,000 participants. These data were used to conduct an alternative dietary exposure analyses, in which these DWCS diaries were used to empirically allocate direct drinking water consumption throughout the day. The risks at the per capita 99.9th percentile did not change considerably relative to the initial~~

~~method of using six equal and fixed events. For indirect drinking water, some preliminary sensitivity analyses indicate that risks at the per capita 99.9th is relatively robust to some of the infant diaries that reported unusually high amounts of formula intake. Finally, Section V summarizes this work, and provides some bullet points to characterize the results presented in this memo.~~

Figure 1. SHEDS-Based Estimated Risks (%aPAD) for Infants GA 300 ft Setback



II. Introduction

Aldicarb is a member of the N-methyl carbamate (NMC) pesticides common mechanism group. Like other NMCs, aldicarb inhibits acetylcholinesterase (AChE) by carbamylation of the serine hydroxyl group located in the active site of the enzyme. NMC toxicity is characterized by maximal inhibition of cholinesterase which occurs rapidly followed by recovery typically occurring within hours. A key consideration in risk assessment is appropriate matching of the duration of exposure with the duration of the toxic effect. Typically, HED's food and water exposure assessments sum exposures over a 24 hour period. This 24 hour total is typically used in acute dietary risk assessment. In the case of the aldicarb, because of the rapid nature of aldicarb toxicity and recovery, it may be appropriate to consider durations of exposure less than 24 hours. Conceptually, a physiologically-based pharmacokinetic model and/or biologically-based dose-response model would be available to account for the dynamic nature of exposure, absorption, toxicity, recovery, and elimination of aldicarb in animals and humans. However, such as model does not exist at this time. In the interim, HED has developed an analysis using information about external exposure, timing of exposure within a day, and half-life of ChE inhibition from rats and humans to estimate risk to aldicarb at durations less than 24 hours. Specifically, HED has evaluated individual eating and drinking occasions and used the ChE half-life information to estimate the residual effects from aldicarb from previous exposures within the day.

Table XX below provides information on the recovery of ChE inhibition in rats and human subjects. For both species, the recovery half-life for RBC ChE inhibition is approximately two hours. At high doses in rat, the half-life is up to approximately 6 hours in females. The estimates of half-life at the lower doses are most relevant for risk assessment and are thus the focus here. As can be seen in the table, the estimated recovery half life of for aldicarb-inhibited AChE in the human is estimated to be on the order of 2 hours using RBC AChE activity. This 2 hour recovery half-life is what is used in this refined dietary exposure assessment which incorporates information on eating/drinking occasions.

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Table XX. Recovery half-life information for ChE inhibition following oral exposure to aldicarb in rats and human subjects

Chemical	Brain		RBC	
	Recovery Half-Life Estimate (hrs)	Upper & Lower Confident Intervals (hrs)	Recovery Half-Life Estimate (hrs)	Upper & Lower Confident Intervals (hrs)
Rat	1.52	1.16-1.99	F (-inf, 0.1) 1.10 (0.1,0.3) 2.91 (0.3,0.5) 3.39 (0.5, Inf) 5.90 M (-inf,0.1) 1.91 (0.1,0.3) 1.20 (0.3,0.5) 1.62 (0.5, Inf) 1.50	F 0.50-2.40 1.96-4.33 2.35-4.90 3.52-9.91 M 1.31-2.79 0.87-1.64 1.19-2.21 0.80-2.82
Human	N/A		2.07	1.74-2.46

II. Dietary Inputs: Anticipated Residues

a Anticipated Residues-Food

Table 2 presents the dietary inputs that were used in both the DEEM-based eating occasion and and SHEDS simulations. These anticipated residues are based on the most updated food residues (PDP (what years) and -- where this information is not available -- the Carbamate Market Basket Survey [note from DJM: the table shows field trial residues being used for pecans] ~~***[note from DJM: presumably, this is only for crops for which PDP did not sample and for which no translation is available***~~), processing factors, percent crop treated estimates, and predicted drinking water concentrations. These data are presented and described in detail in the Aldicarb Dietary Risk Assessment memo, Fort (2006). Following Fort (2006), both food and drinking water concentrations model inputs are expressed in in aldicarb sulfone equivalents. The results from the probabilistic risk assessment models (DEEM and SHEDS) were then converted into aldicarb (parent) equivalents (by multiplying 0.86), and these adjusted exposures are used to calculate risk, based on the acute population adjusted dose (aPAD), which is expressed in in aldicarb parent equivalents.

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Table 2. Food Residues Used in Eating Occasion Analyses (aldicarb sulfone equiv.)

Filename	Commodity	Source/Notes	Total Samples	Est. Max PCT	Total Residues	Range (ppm)
27GFctff.rdf	Grapefruit	Carbamate MBS (NB, Fresh)	213	25%	53	0.00147-0.02906
28GFctfp.rdf	Grapefruit	Carbamate MBS (PB, Proc.)	162	33%	53	0.00147-0.02906
34LEctff.rdf	Lemon	Carbamate MBS	1778	3%	53	0.00147-0.02906
33LIctff.rdf	Lime	Carbamate MBS	762	7%	53	0.00147-0.02906
16OGctff.rdf	Orange	Carbamate MBS (NB, Fresh)	399	13%	52	0.00147-0.02906
17OGctfp.rdf	Orange	Carbamate MBS (PB, Proc.)	399	23%	92	0.00147-0.02906
1Pecanft.rdf	Pecan	Field Trial	275	8%	22	0.005-0.27
46POmnfr.rdf	Potato	PDP (NB, Fresh)	3200	5%	160	0.00758-0.40232
47POmppr.rdf	Potato	PDP (PB, Proc.)	1425	24%	342	0.00758-0.17292
55SWmssp.rdf	Sweet Potato	PDP (NB, Fresh)	432	37%	160	0.00758-0.40232
56SWmcsp.rdf	Sweet Potato	PDP (PB, Proc.)	1755	37%	650	0.00801-0.11825

a Predicted Drinking Water Concentrations

Table 3 presents the drinking water inputs were used in the eating occasion analyses. Fort (2006) provides further description of these scenarios. ~~Table 4 provides a simple calculation of risk based on standard assumptions regarding drinking water consumption.~~ ~~For a typical children's drinking water consumption scenario (10 kg child consuming 1 Liter/day) and the maximum predicted drinking water concentration (6.5 ppb), is approximately 100% of the acute population adjusted dose (aPAD=0.00065 mg/kg/day). As detailed later (Figure 1c), high exposures/risks in the Georgia 300-ft scenario is due to higher reported amounts of infant drinking water consumption, as well as a small subpopulation of infants consuming potato and sweet potatoes containing high residues. As we move toward scenarios with lower predicted~~

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~~drinking water concentrations (e.g., Georgia 1000 ft scenario, NC 300 ft, etc.), the contributions from food tend to drive the estimated exposures at the upper percentile.~~

Table 3. Modeled Drinking Water Scenarios (aldicarb equiv.)

Filename				Notes	
Aldicarb_GACoastalGW_300.csv				GA 300ft setback	
Aldicarb_GACoastalGW_500.csv				GA 500ft setback	
Aldicarb_GACoastalGW_1000.csv				GA 1000ft setback	
Aldicarb_GW_FLCit30.csv				FL 1000ft setback	
Aldicarb_NCCoastalGW_300.csv				NC 300ft setback	
Predicted Drinking Water Concentrations					
Pctile	DW Concentration (ppb)				
	GA 300ft	GA 500ft	GA 1000ft	FL 1000ft	NC 300ft
10%	2.4	1.4	0.3	1.1	0.2
25%	2.8	1.6	0.4	1.4	0.6
50%	3.2	1.9	0.5	1.9	0.7
75%	4.2	2.4	0.6	2.1	0.9
90%	4.8	2.8	0.7	2.5	1.0
80%	4.4	2.5	0.6	2.2	0.9
90%	4.8	2.8	0.7	2.5	1.0
95%	5.2	3.0	0.7	2.6	1.1
97.5%	5.5	3.1	0.8	2.7	1.1
99%	6.0	3.5	0.8	2.8	1.3
100%	6.5	3.7	0.9	3.0	1.3

~~**Table 4. Calculated Exposures for Standard DW Consumption (6.5 ppb)**~~

~~Exposure Routes~~	~~Child~~	~~Adult Female~~	~~Adult Male~~
~~Amount Water Consumed (Liters/day)~~	~~1~~	~~1.5~~	~~2~~
~~Drinking Water Concentration, ppb (ug ai/Liter)~~	~~6.5~~	~~0.0065~~ ~~**[should this be 6.5?]**~~	~~0.0065~~ ~~**[should this be 6.5?]**~~
~~Drinking Water Exposure (ug ai/day)~~	~~6.5~~	~~0.00975~~	~~0.013~~
~~Unit Conversion (ug=>mg)~~	~~1/1000~~	~~1/1000~~	~~1/1000~~
~~Drinking Water Exposure (mg ai/day)~~	~~0.00650~~	~~0.00001~~	~~0.00001~~
~~Bodyweight (kg)~~	~~10~~	~~60~~	~~70~~
~~Drinking Water Exposure (mg ai/kg bwt/day)~~	~~0.00065~~	~~0.00016~~	~~0.00019~~
~~aPAD~~	~~0.00065~~	~~0.00065~~	~~0.00065~~
~~Computed Estimated Risks~~	~~100%~~	~~25%~~	~~29%~~

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III. Method for Estimating Exposure Based Risks on Eating/Drinking Occasions

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a. ~~a.~~ **Baseline Analysis….here.**

~~**Accounting for Reversibility in Cholinesterase Inhibition**~~

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~~**…Subsection Needs Work….**~~

~~Over the last few years, the Agency presented several methods for addressing this half-life issue.~~

~~in two SAP meetings on the NMC CRA~~

~~November 10th, 2003, "Physiologically-Based Pharmacokinetic/Pharmacodynamic Modeling: Preliminary Evaluation and Case Study for the N-Methyl Carbamate Pesticides~~

~~December 3rd, 2004 FIFRA Science Advisory Panel Meeting "The N-Methyl Carbamate Cumulative Risk Assessment: Strategies and Methodologies for Exposure Assessment" ([~~ HYPERLINK "http://www.epa.gov/scipoly/sap/meetings/2004/index.htm" ~~])~~

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~~December 2, 2004 - Use of Pharmacokinetic Data to Refine Carbaryl Risk Estimates from Oral and Dermal Exposure~~

~~Bottom Line: applying logic of peak vs AUC, but this is an exposure modeling exercise: no absorbed dose, and certainly no PBPK/PK effects…maybe next year.~~

Table 1 summarizes the results of the DEEM and SHEDS analyses at the per capita 99.9th percentile for the eating/drinking occasion analysis using a two hour half-life for aldicarb. These results are presented as % of the acute Population Adjusted Dose (aPAD). This aPAD was derived from a BMDL10 of XXX from human subjects and a 20X total uncertainty factors [10X for intraspecies extrapolation (ie, within the human population) and 2X FQPA safety factor to account for increased sensitivity of infants and children]. For food only, these levels are below the level of concern for all subpopulations. Four drinking water concentration scenarios were modeled for aldicarb: 3 ground water scenarios for aldicarb use on peanuts/cotton in Georgia with an assumption of 300 ft, 500 ft and 1000 ft well set-backs, and one ground water scenario for aldicarb use on Florida citrus with a 1000 ft set-back. The estimated risks at the per capita 99.9th percentile are below the level of concern for all four scenarios. for all subpopulations except ~~for~~ infants. For infants, the estimated risks at the per capita 99.9th percentile exceeds the level of concern under the Georgia 300 ft scenario (139% - 147% of the aPAD). The estimated risks for the Georgia-GW 300 foot setback distance is at 100% of the aPAD at approximately the per-capita 99.7 percentile of the infant subpopulation.

Table 1. Estimated Risks at the Per Capita 99.9th Percentile (2 hr half-life)

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Subpopulation	DEEM-Based Eating Occasion	
	Food Only	

USPop	34%	58%	44%	36%	42%
All Infants	41%	147%	88%	43%	80%
Children 1-2 yrs	72%	95%	80%	76%	78%
Children 3-5 yrs	60%	77%	64%	52%	62%
Children 6-12 yrs	46%	48%	45%	42%	44%
Youth 13-19 yrs	28%	46%	33%	28%	30%
Adults 20-49 yrs	29%	54%	38%	30%	36%
Adults 50+ yrs	34%	47%	37%	34%	37%
Females 13-49 yrs	29%	50%	35%	28%	34%
		SHEDS-NMC Eating Occasion			
Subpopulation	Food Only	GA-GW 300 ft	GA-GW 500 ft	GA-GW 1000 ft	FL-SW 1000 ft
USPop	35%	55%	42%	36%	41%
All Infants	41%	139%	85%	42%	77%
Children 1-2 yrs	77%	91%	80%	78%	79%
Children 3-5 yrs	57%	71%	61%	57%	60%
Children 6-12 yrs	43%	46%	44%	43%	44%
Youth 13-19 yrs	31%	44%	34%	31%	33%
Adults 20-49 yrs	30%	52%	37%	30%	36%
Adults 50+ yrs	32%	45%	36%	33%	35%
Females 13-49 yrs	30%	50%	37%	30%	36%

These eating occasion results are based on several major assumptions: (i) 2 hour half-life, and (ii) allocation of direct drinking water consumption based on six equal and fixed occasions .

ba. DEEM-Based Eating Occasion Analyses

The DEEM-FCID model has been used extensively by the Agency to conduct probabilistic dietary risk assessments. The overall concept has been reviewed ~~and approved~~ by a FIFRA Science Advisory Panel in 2000 (http://www.epa.gov/scipoly/sap/meetings/2000/index.htm). A general overview of the DEEM model is provided in each dietary risk assessment, and is not reproduced here. As noted in the DEEM reports, ~~"Daily totals for food and foodform consumption used"; in other words,~~ DEEM simulates dietary exposure by randomly drawing a residue for each commodity-food form, and multiplies that by the total amount consumed throughout the day. These commodity-specific exposures are then summed to produce a total daily exposure which is converted to a ug/kg bw-day basis To the extent that the individual may have consumed those foods and drinking water throughout the day, the timing and amounts of those exposures on each of those eating occasions is not provided by the DEEM model. However, since that information is available in the USDA CSFII food diaries, we can use that data, together with the DEEM simulated outputs to obtain a DEEM-based estimate of dietary exposure by eating occasion. This Section highlights the mechanics of those calculations.

Figure 21 depicts outputs from the three different DEEM-FCID reports: (i) Summary Table, (ii) Plot File, and (iii) Critical Exposure Commodity (CEC) Analyses. The summary table, depicted in Figure 21a, displays the estimated exposure and risks (%aPAD) at the per capita 95th, 99th, and 99.9th percentiles. This report also specifies the percent of all food diaries that are 'users'. A food diary is considered a 'user' if one or more of the foods for which anticipated residues have been assigned, including drinking water, was consumed. In this example, 89.38% of all infant-diaries are 'users'; that is, approximatey 90% of these infants consuming any of these foods and/or drinking water (Section III provides further description on Drinking Water Consumption patterns). The Plot File presents the total number of diaries (N=2,940), the total projected person-days (N=7,548,892), and the projected person-days in each 'exposure bin' for all 'simulated users'. based on the number of iterations specified in the Mmonte Ccarlo simulation (200 iterations). The data in this plot file can be used to construct the projected per capita estimates for the entire subpopulation, as depicted in Figure 21b.

DEEM'sThe 'CEC' report provides a summary of exposure at the upper percentile. The first half of the CEC report provides shares of total exposure by commodity; in this case, indirect water, food form=130 accounts for 63.52% of total exposures between the 95th and 100th percentile. This indirect drinking water is primarily infant formula, with food form=130 (cooking status=uncooked, form=dried, cooking method=not specified) referring to the powder component. Other forms of both direct and indirect drinking water, as well as foods, constitute the remaining shares of total exposure at this upper percentile. In this case, the top 5% of simulated exposure diaries are saved in this output file.

The second part of the CEC report provides the foods consumed and residues drawn for all simulated diaries at upper 95th through 100th percentile. Figure 1c presents a few selected simulated diaries; the total number of diaries in this top 5 percentile is determined by the total number of diaries in the subpopulation (N=2,940), the total number of iterations (200 iterations), and the sampling weights for the simulated diaries that tend to fall in this upper percentile. ~~If all of the diaries were equally weighted, then 200 iterations would produce a total of 588,000 (=2940x200) simulated person-days, with 29,400 person-days (=588,000x0.05) in the top 5 percentile.~~

The individual demographic information is provided (CSFII Household-Person-Day identification) so that one can go back to the USDA CSFII food diaries to link other information that is not used by the DEEM model. For the eating occasion analyses, ~~we retrieved~~ information on the amount and timing of all eating occasions was retrieved from the CSFII diaries, and then merged ~~that data~~ with the simulated *[note from DJM – what do we mean when we say "simulated"? Can we eliminate this word?]* output from the CEC report. This process is depicted in Figure 2. Figure 2 a. depicts the exposure for a particular simulated diary.

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In this example, DEEM outputted 29,138 person-days (records), from this simulation. The DEEM CEC report has the following limitations: (i) a maximum of 40,000 records is outputted, (ii) the lower interval for which CEC focuses upon is the 95th percentile (any range between 95th and 100th percentile), (iii) foods contributing less than 1% of the simulated daily exposure are not saved in the simulated output (lower half). It is important to ensure that the number of actual (and printed) records do not exceed the 40,000 limit, and that the two day CSFII sampling weights are used to obtain an accurate DEEM-based estimate from this CFC output. If too many iterations are specified in the DEEM simulation, then DEEM may print out more than this maximum limit, however, these outputted records may not provide a comprehensive, random set of the top 5 percentile. Agency risk assessors typically specify 1,000 iterations when conducting probabilistic risk assessments using DEEM, since the model is extremely efficient and quick in conducting the Monte Carlo simulations. However, due to the limitations listed above, fewer iterations were specified here to obtain a complete set of records for the Top 5 percent. While these number of iterations conducted here were significantly lower than the typical 1000 iterations used in OPP risk assessments in order not to exceed the 40,000 record limit, the estimates were very similar to baseline results found with 1000 iterations.

Figure 2. Example of DEEM Outputs

Figure 2a. DEEM Summary Table (AC7)

```
DEEM-FCID ACUTE Analysis for ALDICARB                              (1994-98 data)
Residue file: Water GA 300 final.R98                  Adjustment factor #2 used.
Daily totals for food and foodform consumption used.
MC iterations = 200      MC list in residue file     MC seed = 10
===============================================================================
Summary calculations (per capita):
                    95th Percentile      99th Percentile      99.9th Percentile
                   Exposure   % aRfD    Exposure   % aRfD    Exposure   % aRfD
                  ---------- --------  ---------- --------  ---------- --------
All infants:        0.000852   131.14    0.001318   202.79    0.002171   333.99
Aldicarb Equiv./1   0.000733   112.78    0.001133   174.39    0.001867   287.23

       Percent of Person-Days that are User-Days =  89.38%
1 - Values converted to Aldicarb (parent) equivalents by multiplying (0.86).
```

Figure 2b. DEEM Plot File (PLT) - Plot generated in Excel based on DEEM bins

```
Total person days (weighted & unweighted) =,      7548892,         2940
Total user days   (weighted & unweighted) =,      6747448,         2642
Bin totals based on 200 iterations.
```

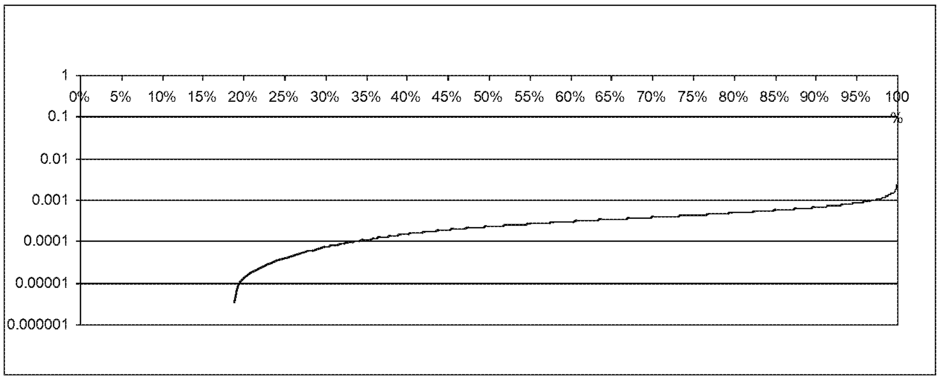


Figure 2c. DEEM Contribution Exp (CEC)

```
================================================================================
Low percentile for CEC records: 95     Exposure (mg/day) =     0.000852
High percentile for CEC records: 100   Exposure (mg/day) =     0.010137
Number of actual records in this interval: 29138
Food,      FF,      N  ,  Percent,  Food Name
--------,  ---,     -----,  -------,  -------------
86020000,  130,   20921,   63.52%,  Water, indirect, all sources-Uncooked; Dried; Cook Meth N/S
86010000,  110,   16747,   12.61%,  Water, direct, all sources-Uncooked; Fresh or N/S; CookM N/S
86020000,  240,    4772,   10.61%,  Water, indirect, all sources-Cooked; Canned; Cook Meth N/S
 - - - - more statistics for different commodities and commodity-food forms - - - -
 1033660,  211,      48,    0.32%,  Sweet potato-Cooked; Fresh or N/S; Baked
 1033000,  212,     105,    0.24%,  Potato, tuber, w/o peel-Cooked; Fresh or N/S; Boiled
95002640,  210,       1,    0.00%,  Peanut, butter-Cooked; Fresh or N/S; Cook Meth N/S

Demographic data for each record, Exposure contribution data by food (Selected Records):
PID,  HH-Indiv, Day,Sex,  Age,    Bw-kg,  Nf,  Nx,   Tot Expos,  Samplwt,
      Food,      FF,  Amt(g),   Residue , Adj#1, Adj#2,   Contributn,  Percnt
19984 ,46309-02 , 2  ,M   ,10M   ,  9.99 , 2  ,   1 ,  0.0101373 ,  1844 ,
      1033660  ,211,  246.1 ,  0.402325 , 1.00 , 1.00 ,  0.0099013 ,   97.67
      86020000 ,240,  368.3 ,  0.003900 , 1.00 , 1.00 ,  0.0001436 ,    1.42
18391 ,26837-02 , 2  ,M   ,1M    ,  3.63 , 2  ,   1 ,  0.0035422 ,  3066 ,
      86010000 ,110,  118.3 ,  0.006300 , 1.00 , 1.00 ,  0.0002050 ,    5.79
      86020000 ,130, 1926.1 ,  0.006300 , 1.00 , 1.00 ,  0.0033370 ,   94.21
```

Figure 3. Example Illustrating Method to Compute Eating Occasion Exposure from DEEM CEC Output

Data on the timing and amounts of foods and indirect drinking water throughout the day are taken from the CSFII food diaries, and merged into the respective DEEM CEC diaries to obtain eating occasion estimates. Assumptions are required regarding the timing and amounts of direct drinking water consumption since that information is not available in CSFII. One option, depicted here, is to equally allocate the total amount over six fixed events: 240 minutes after midnight or 6 am, 9 am, 12 noon, 3 pm, 6 pm, and 9 pm. For this particular simulation, total exposure for this simulated diary is 0.00356 mg/kg/day, or 548% of the aPAD. Under the eating occasion approach, the maximum cumulative exposure with a two hour half-life is 0.000773 mg/kg, or 119% of the aPAD.

Source	Amt (ml/Day)	Residue (mg/L)	Exposure (mg/day)	Exposure (mg/kg/day)	Share of Exposure
Direct DW	118.3	0.00633	0.00075	0.00021	5.80%
Indirect DW	1926.1	0.00633	0.01219	0.00336	94.20%
Total Daily			Total=	**0.00356**	100%
				548%	

With a two hour half-life:
Discount Rate = (0.5)^(Time_Diff/120)
Discounted Exposure(t) = Cumulative Exposure(t-1) x Disc Rate

HHID-SPNUM-DAY=26837-3-2, Bwt=3.63 kg, SIM_N=1 of 119.

Source	Direct DW Allocate	Amt (mL/EO)	Residue (mg/L)	Time Of Day (minutes)	Exposure (mg/kg/EO)
Indirect DW	-	214	0.00633	240	0.00037
Indirect DW	-	214	0.00633	360	0.00037
Direct DW	1	19.7	0.00633	360	0.00003
Indirect DW	-	214	0.00633	480	0.00037
Direct DW	2	19.7	0.00633	540	0.00003
Indirect DW	-	214	0.00633	600	0.00037
Indirect DW	-	214	0.00633	720	0.00037
Direct DW	3	19.7	0.00633	720	0.00003
Indirect DW	-	214	0.00633	840	0.00037
Direct DW	4	19.7	0.00633	900	0.00003
Indirect DW	-	214	0.00633	1080	0.00037
Direct DW	5	19.7	0.00633	1080	0.00003
Indirect DW	-	214	0.00633	1200	0.00037
Direct DW	6	19.7	0.00633	1260	0.00003
Indirect DW	-	214	0.00633	1320	0.00037

Exposure (mg/kg/EO)	Time of Day	Time Diff (Last EO)	Disc Rate	Discntd Exposure	Cumltive Exposure
0.00037	240				3.72E-04
0.00041	360	120	0.50	1.86E-04	5.94E-04
0.00037	480	120	0.50	2.97E-04	6.69E-04
0.00003	540	60	0.71	4.73E-04	5.06E-04
0.00037	600	60	0.71	3.58E-04	7.30E-04
0.00041	720	120	0.50	3.65E-04	**7.73E-04**
0.00037	840	120	0.50	3.86E-04	7.58E-04
0.00003	900	60	0.71	5.36E-04	5.69E-04
0.00041	1080	180	0.35	2.01E-04	6.09E-04
0.00037	1200	120	0.50	3.04E-04	6.76E-04
0.00003	1260	60	0.71	4.78E-04	5.11E-04
0.00037	1320	60	0.71	3.62E-04	7.33E-04
0.00356	**=sum**			**max=**	**7.73E-04**
548%					**119%**

Eating occasion exposures/risks calculated for each simulated person-day diary

Figure 4a. Plot of Total Daily and Maximum Cumulative Eating Occasion Exposures

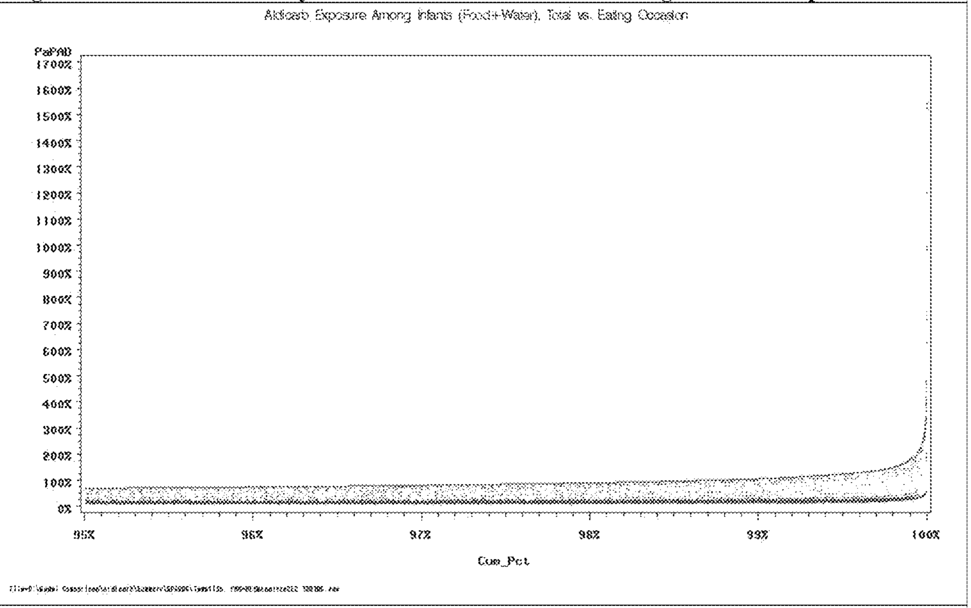


Figure 4b. Distribution of Total Daily and Eating Occasion Exposures

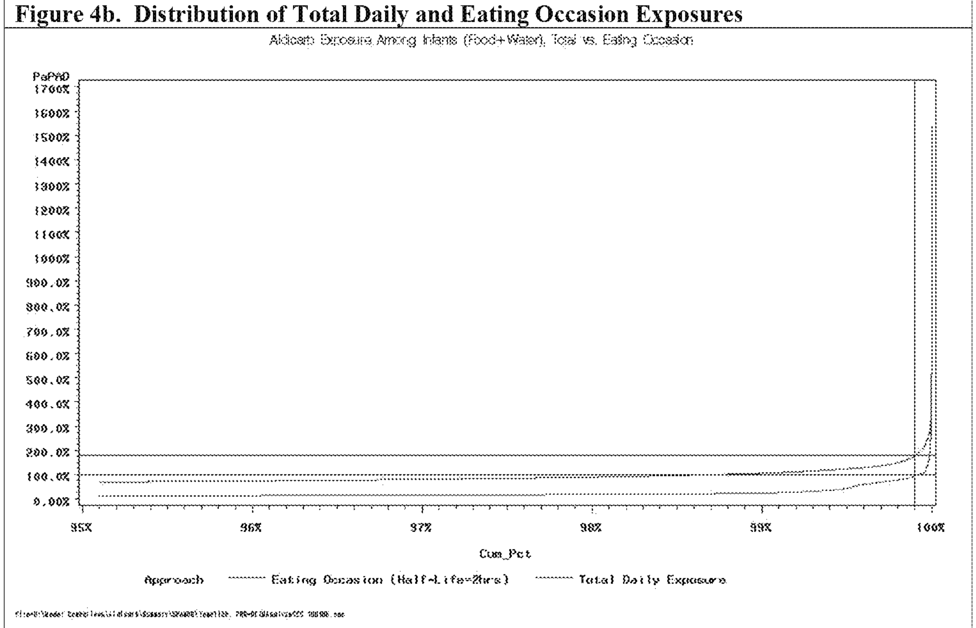


Figure 3 illustrates how eating occasion estimates were computed from the DEEM CEC output. Data on the timing and amounts of foods and indirect drinking water consumed throughout the day are extracted from the CSFII food diaries, and merged into the respective DEEM CEC diaries to obtain eating occasion estimates. The maximun cumulative exposure was computed for each eating occasion for each simulated person-day diary in the DEEM CEC report (Top 5 percentile) Assumptions are required on the timing and amounts of *direct* (as opposed to *indirect* which are supplied by the CSFII) drinking water consumption throughout the day since ~~that~~ direct water consumption data is not available in CSFII. One option, depicted here, is to evenly allocate the total amount over the day on 6 fixed events: 240 minutes after midnight or 4~~6~~ am, 9 am, 12 noon, 3 pm, 6 pm, and 9 pm. Sensitivity analyses for using two other options for allocating Direct Drinking Water consumption throughout the day are presented in Section III. The total daily exposure for this particular simulated diary is 0.00356 mg/kg/day, or 548% of the aPAD, while the maximum cumulative exposure with a two hour half-life is 0.000773 mg/kg, or 119% of the aPAD under the eating occasion approach.

T~~We computed~~ the maximum cumulative exposure was computed for each eating occasion for each simulated person-day diary in the DEEM CEC report (Top 5 percentile). Figure 4a illustrates the total daily exposure values for these top 5 percent of simulated diaries, together with the paired eating occasion values. Re-sorting the eating occasion values enables us to calculate the 99.9th percentile for the DEEM-based eating occasion analyses, as depicted in Figure 4b; the two distributions are overlapped and plotted over the per capita percentiles. ***[Note from DJM: do we need Figures 4a and 4b and the accompanying text in this paragraph]***

~~As indicated above, it is important to make sure the number of actual (and printed) records do not exceed the 40,000 limit, and that the two-day CSFII sampling weights are used to obtain an accurate DEEM-based estimate from this CEC output. If too many iterations are specified in the DEEM simulation, then DEEM may print out more than this maximum limit, however, these outputted records may not provide a comprehensive, random set of the top 5 percentile. The total projected population is needed to determine the per capita 99.9th percentile. Table 5 depicts the number of iterations specified in the DEEM simulations. While these numbers were significantly lower than the typical 1000 iterations used in OPP risk assessments, the estimates were very similar to baseline results with the 1000 iterations.~~

~~Table 5. DEEM Simulations: Number of Iterations & Projected Person-Days~~

~~Subpop~~	~~# Diaries~~	~~# Iterations~~	~~Est. Total # Records in Top 5%~~	~~Projected Population~~	~~Total Simulated Person-Days~~
~~USPop~~	~~40,476~~	~~10~~	~~20,238~~	~~517,917,162~~	~~5,179,171,620~~
~~Infants~~	~~2,940~~	~~200~~	~~29,400~~	~~7,548,892~~	~~1,509,778,400~~
~~1to2~~	~~4,114~~	~~100~~	~~20,570~~	~~16,130,358~~	~~1,613,035,800~~
~~3to5~~	~~8,464~~	~~75~~	~~31,740~~	~~23,848,944~~	~~1,788,670,800~~
~~6to12~~	~~4,052~~	~~100~~	~~20,260~~	~~52,701,450~~	~~5,270,145,000~~
~~13to19~~	~~2,408~~	~~100~~	~~12,040~~	~~51,320,412~~	~~5,132,041,200~~
~~20to49~~	~~9,296~~	~~75~~	~~34,860~~	~~233,967,096~~	~~17,547,532,200~~
~~50Plus~~	~~9,202~~	~~75~~	~~34,508~~	~~132,400,010~~	~~9,930,000,750~~
~~F13to49~~	~~5,840~~	~~100~~	~~29,200~~	~~142,817,022~~	~~14,281,702,200~~

b Stochastic Human Exposure and Dose Simulation (SHEDS) Model

~~The Stochastic Human Exposure and Dose Simulation (SHEDS) model, developed by the Agency's Office of Research and Development, National Exposure Research Laboratory, was also used in this aldicarb eating occasion analyses. This version that we are using, SHEDS-NMC, was developed for the N-Methyl Carbamate Cumulative Risk Assessment (NMC CRA). This aldicarb eating occasion risk assessment, and the NMC CRA, is the first time that SHEDS-NMC has not been used by the Agency. SHEDS-Wood was used by the Office of Pesticide Programs to assess children's exposure to wood preservatives (CCA) from treated decks and playsets. However, that version, presented to the FIFRA Science Advisory Panel in 2001 and 2002 (http://www.epa.gov/scipoly/sap/meetings/2002/index.htm), did not include a dietary component. There is another version of SHEDS that includes a longitudinal dietary module which has been used in other studies. Having that longitudinal aspect, like SHEDS-Wood Preservatives, may be useful for chronic and cancer risk assessments. The drawback to using that version of SHEDS is that it is based on a different model design; utilizing the U.S. Census to develop its reference population, using bins to stochastically develop longitudinal consumption patterns — which leads to different expected (and realized) frequencies of using the CSFII food diaries, and weighting these simulated exposure person-days to calculate a per-capita estimates.~~

For the NMC CRA, the Office of Pesticide Programs used~~wanted~~ a version of SHEDS (termed SHEDS-NMC) that utilized the two-day CSFII respondents as its reference population, fixed the number of 'iterations' that each diary was used in a simulation to the same frequency, and utilized the corresponding USDA CSFII sampling weights to calculate per capita exposures and risks. This version of SHEDS also ~~We also wanted to~~ restricted the method for drawing anticipated food residues in the Monte Carlo simulations to the standard approach used by the other models (DEEM-FCID, Calendex, Lifeline and CARES). In this way, SHEDS-NMC best approximates the assumptions, data, and algorithms used in the standard models currently used by OPP in its risk assessments. Table 6 compares the use of the CSFII data by SHEDS-NMC and DEEM-FCID. This conformity enables us to use SHEDS-NMC and focus upon the effects of accounting for eating occasions, without complicating this detailed intra-day analyses with other differences in modeling design. The result is that for acute dietary risk assessment, SHEDS-NMC produces similar 'total daily' results as DEEM-FCID, CARES and Lifeline, in addition to producing eating occasion results. Table 7 presents the baseline figures from DEEM and SHEDS of total daily exposure (%aPAD) at the per capita 99.9th percentile. As can be seen, estimated exposures and associated risks are similar between the two models and differ by less than 10%.

Table 6 Comparison of SHEDS-NMC and DEEM-FCID		
Variable	**DEEM-FCID (2.2)**	**SHEDS-NMC**
#Diaries Used (RefPop) Food Only Food+Water	(CSFII 2-Day) 41,214 40,476	(CSFII 2-Day) 41,214 41,214
Model Weights (Per capita 99.9th)	CSFII 2-Day	CSFII 2-Day
Frequency Used in MC simulations	User Specified	User Specified

Data Available For Eating Occasion	Top 5%, Max=40K records	All Simulated Records

Table 7. Comparison of DEEM and SHEDS Baseline Risks@99.9th

Subpopulation	DEEM Total Daily Exposure/Risks				
	Food Only	GA-GW 300 ft	GA-GW 500 ft	GA-GW 1000 ft	FL-SW 1000 ft
USPop	35%	119%	74%	39%	68%
All Infants	42%	285%	168%	53%	154%
Children 1-2 yrs	77%	145%	98%	80%	92%
Children 3-5 yrs	64%	135%	93%	66%	88%
Children 6-12 yrs	50%	87%	60%	49%	57%
Youth 13-19 yrs	30%	91%	58%	33%	52%
Adults 20-49 yrs	30%	94%	58%	32%	53%
Adults 50+ yrs	35%	72%	49%	35%	46%
Females 13-49 yrs	30%	92%	57%	32%	52%
Subpopulation	SHEDS Total Daily Exposure/Risks				
	Food Only	GA-GW 300 ft	GA-GW 500 ft	GA-GW 1000 ft	FL-SW 1000 ft
USPop	37%	116%	73%	39%	67%
All Infants	41%	278%	160%	53%	148%
Children 1-2 yrs	82%	144%	99%	84%	94%
Children 3-5 yrs	60%	131%	91%	62%	84%
Children 6-12 yrs	45%	84%	58%	47%	55%
Youth 13-19 yrs	32%	88%	58%	33%	52%
Adults 20-49 yrs	31%	91%	57%	32%	52%
Adults 50+ yrs	33%	70%	48%	35%	45%
Females 13-49 yrs	31%	89%	57%	32%	52%
Subpopulation	Ratio DEEM/SHEDS				
	Food Only	GA-GW 300 ft	GA-GW 500 ft	GA-GW 1000 ft	FL-SW 1000 ft
USPop	0.96	1.03	1.02	1.00	1.02
All Infants	1.01	1.02	1.05	1.00	1.04
Children 1-2 yrs	0.94	1.01	0.99	0.95	0.98
Children 3-5 yrs	1.07	1.03	1.03	1.07	1.05
Children 6-12 yrs	1.09	1.04	1.03	1.03	1.04
Youth 13-19 yrs	0.92	1.02	0.99	0.99	1.00
Adults 20-49 yrs	0.98	1.03	1.01	1.00	1.02
Adults 50+ yrs	1.04	1.03	1.03	1.01	1.02
Females 13-49 yrs	0.97	1.02	1.00	0.97	1.00

~~c Sensitivity Analyses on Half-Life~~

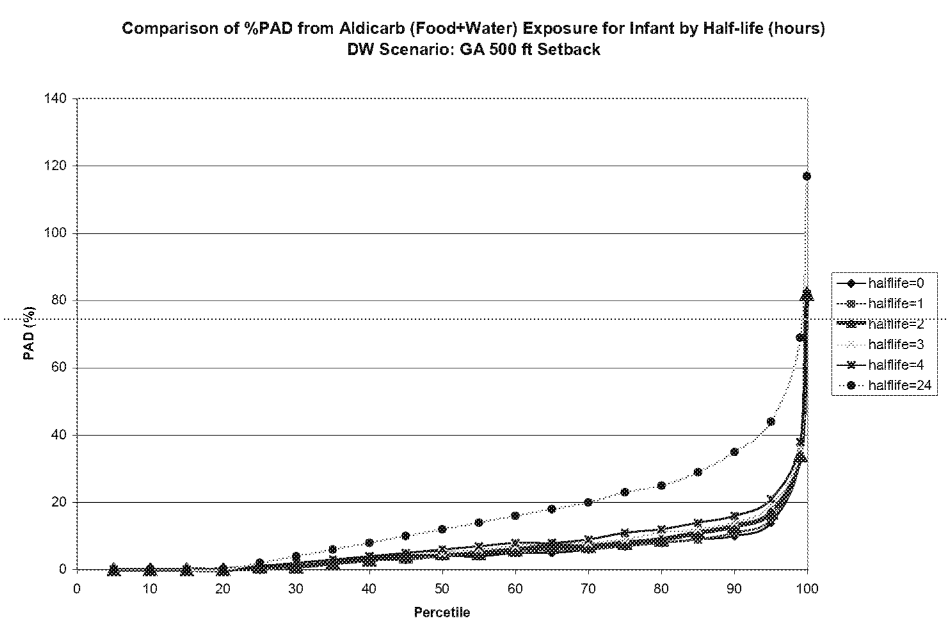
~~We estimated the risks assuming various half-life parameters to evaluate the robustness of these eating occasion results with respect to this particular parameter. Table 8 compares the Eating Occasion Risks at the per capita 99.9th percentile with a two-hour versus a three-hour half-life for aldicarb. The change in this parameter has a surprisingly little impact at this percentile. Figure 4 depicts these results for the entire distribution for the infant subpopulation under the Georgia 500 ft setback scenario. While the exposure/risk values change at other percentiles, this preliminary~~

~~sensitivity analyses suggest that risks at the per capita 99.9th percentile is relatively robust to moderate changes in this half-life parameter.~~

~~**Table 8. Comparison of E.O. Risks with 3 hr and 2 hr half-lives**~~

Subpopulation	Risk (%aPAD) at the Per Capita 99.9th% Food Only	GA-GW 300 ft	GA-GW 500 ft	GA-GW 1000 ft	FL-SW 1000 ft
2 hr half-life					
Infants	41%	139%	85%	42%	77%
1-2 yrs	77%	91%	80%	75%	70%
3-5 yrs	57%	71%	61%	57%	60%
6-12 yrs	43%	46%	44%	43%	44%
13-19 yrs	31%	44%	34%	31%	33%
20-49 yrs	30%	52%	27%	30%	36%
50Plus	32%	45%	26%	32%	35%
Females 13-49 yrs	30%	50%	27%	30%	36%
3 hr half-life					
Infants	41%	139%	85%	42%	77%
1-2 yrs	77%	91%	80%	75%	70%
3-5 yrs	57%	72%	61%	58%	60%
6-12 yrs	43%	47%	45%	44%	45%
13-19 yrs	31%	45%	34%	31%	33%
20-49 yrs	30%	53%	27%	30%	36%
50Plus	32%	45%	26%	32%	35%
Females 13-49 yrs	30%	50%	27%	30%	36%
Ratio 3 hr/2 hr					
Infants	1.000	1.001	1.003	1.008	1.000
1-2 yrs	1.003	1.007	1.002	1.007	1.003
3-5 yrs	1.003	1.015	1.006	1.005	1.006
6-12 yrs	1.003	1.024	1.008	1.003	1.008
13-19 yrs	1.005	1.024	1.002	1.007	1.008
20-49 yrs	1.003	1.009	1.002	1.003	1.004
50Plus	1.000	1.007	1.002	1.003	1.005
Females 13-49 yrs	1.001	1.014	1.002	1.003	1.003

Figure 5. Sensitivity Analyses on Half-Life Parameter: Infant GA 500 ft Scenario



IV. Drinking Water Consumption Patterns

a CSFII Data

As noted in Section II above, the relatively high contributions from drinking water in some scenarios is due to high amounts of consumption among infants and toddlers. ~~As Table 9 indicates, d~~Drinking water intake differs between these two subpopulations~~,~~; even among newborns versus 6-12 month old 'infants'~~. As Table 9 indicates,~~; infants receive much of their exposures from indirect drinking water, generally via formula intake, while toddlers receive much of their drinking water exposures through consumption of direct drinking water, as well as indirect drinking water.

~~Table 9. DEEM-Based Major Contributors at the 99.9th-100th For Infants and Toddlers~~

Food	Infants				1to2 yr olds			
	Food Only	GA-GW 300-ft	GA-GW 500-ft	GA-GW 1000-ft	Food Only	GA-GW 300-ft	GA-GW 500-ft	GA-GW 1000-ft
Coffee	..	..	..	.	.	..	..	..
Grapefruit	0%	..	..	0%	0%	0%	0%	0%
Lemon	0%	..	..	.	0%	..	..	..
Lime	..	..	..	.	.	..	..	..
Orange	3%	0%	0%	1%	8%	2%	5%	7%
Peanut	0%	..	..	0%	0%	0%	0%	0%
Pecan	..	..	..	.	.	..	..	0%
Potato	56%	4%	12%	46%	66%	27%	52%	65%
Sweet potato	41%	3%	9%	34%	26%	11%	21%	26%
Water-Direct	..	12%	10%	3%	.	44%	16%	4%
Water-indirect	..	81%	69%	15%	.	16%	6%	4%
Total	100%	100%	100%	100%	100%	100%	100%	100%

Figures 6a and 6b plot~~s~~ drinking water consumption from the CSFII/FCID data base, by age group, in mL/day and mL/kg bwt/day, respectively. Similarly, Figures 6a and 6b plots drinking water consumption, by age group, in mL/day and mL/kg bwt/day, respectively. As Figure 6b depicts, infants tend to have higher overall drinking water consumption rates (mL/kg bwt/day) than children, which in turn, tend to have higher consumption rates than adults. Figure 6a depicts some outliers in reported drinking water consumption amounts. For example, one teenager (HHID-SPNUM-DAY: 22749-3-1) reported consuming over 20 Liters/day (direct), while a few people reported consuming more than 10 Liters/day, some via beverages (indirect). ***[Comment from DJM: since it is mostly children we are dealing with here and all other populations are fine, do we need to highlight this? Maybe we do.]***

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Figure 6a.

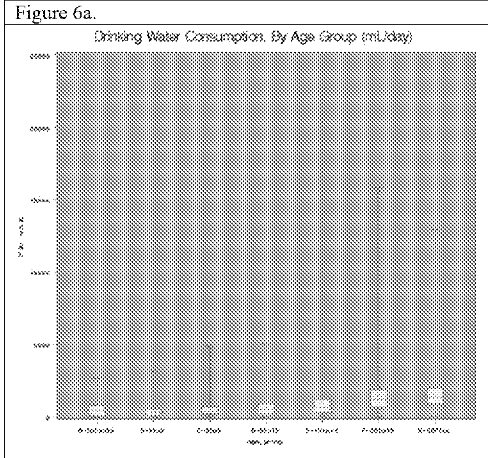


Figure 6b.

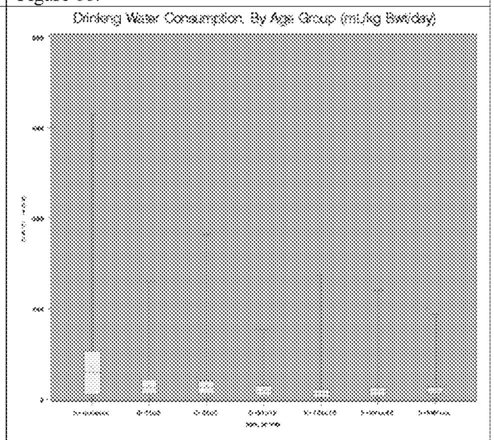


Figure 6c.

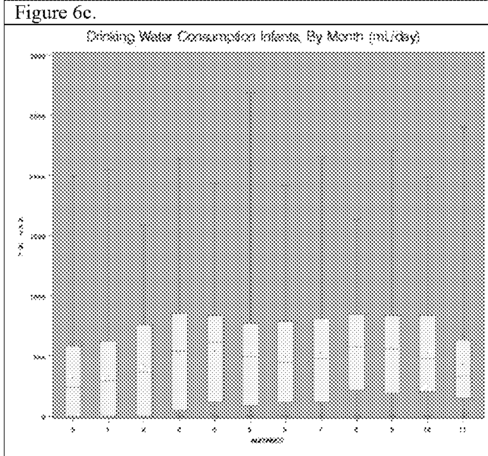
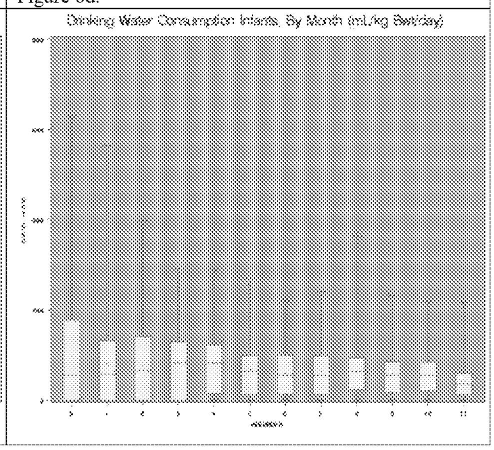


Figure 6d.



There are a few significant consumers among infants and toddlers (1to2 yr olds). Figure 6c depicts the high end, in particular, ~~couple~~two newborn infants that weighed less than 4 kg, and consumed nearly 2 liters of water (primarily through formula). A preliminary inspection of these food diaries indicate that a set amount of formula was reportedly prepared and consumed by the infants on multiple occasions throughout the day. The first infant diary (28892-2-1) was a newborn (0 month old) weighing 3.2 kg, indicated that a total of 8 oz of formula (6 ounces consumed directly + 2 oz used to prepare 0.25 cup of dry rice cereal) was prepared and consumed at 8:00 am, 9:30, 11, 1:30, 4:30, 6:00, 10 and 11:30 pm; an additional 4 oz of formula alone was prepared/consumed at 1:00 am. The second infant-dairy (26837-3-2) was a one month old that weighed 3.6 kg, and consumed 8 oz of formula at 4:00 am, 6, 8, 10, 12, 2, 6, 8 and 10 pm.

Sensitivity Analyses

To evaluate the robustness of the results for the infant subpopulation, we conducted some sensitivity analyses using both SHEDS and the DEEM-based approach, in one case, reducing the reported amounts consumed by 50 percent, and in the other case, dropping these diaries altogether. We found that the results did not change considerably in either analyses, even when the reported amounts consumed was reduced for an expanded set (top five) of diaries.

b Bayer Drinking Water Consumption Survey (Direct)

As noted above, for direct drinking water, the USDA CSFII collected information on only the total amount ~~of Direct Drinking Water~~ consumed during the survey date; it did not collect information on the per-occasion amounts and timing of drinking water events ~~consumed~~ throughout the day. For newborn infants, indirect drinking water (via formula) is their primarily source of water consumption; and that information is available in the CSFII. But the primary source of water intake for many toddlers, older children and adults is direct drinking water. To address this deficit, Bayer CropScience sponsored a study in 2004 on direct drinking water consumption entitled, "Drinking Water Consumption Survey" ~~in 2004 on direct drinking water consumption~~, and submitted their report and the raw data to the Agency. The objective of this study was to obtain a distribution of water intake for a 24-hour time period that was nationally representative sample of the US pPopulation. Participants recorded their direct drinking water consumption (time of day and amount consumed) over a one-week (7 days) period during ~~Collection Dates:~~ Summer 2000 (August), and Winter 2001 (March). A total of 4,198 individuals from 2,154 households participated in the survey, providing a total of 27,282 person-day diaries, i.e., 93% of the total of all participants returned diaries for all 7 days.

According to the report (Barraj, L.M. et.al. (2004), Exponent®, Inc.; National Product Database (NPD) Group), one of the potential uses of these data is to refine a probabilistic exposure assessment:

> *"It may be possible, using the information collected by the DWCS to "allocate" the total daily water consumption amount reported in the CSFII into various drinking occasions. Specifically, if each subject in the CSFII survey was randomly matched to subjects in the DWCS, based on survey season, region, age, gender, and total amount of drinking water consumed per day, then the total amount reported by that CSFII participant can be allocated to the same number of drinking occasions as those reported by the matching DWCS participant. Similarly, the proportion of the total daily water consumption allocated to each of these drinking occasions can be assumed to be similar to that reported by the matching DWCS participant. This approach would then allow a less than 24-hour assessment of both food and drinking water (aggregate assessment) for a pesticide."* (Bayer 2005, p.17)

Figures 7a and 7b were taken from DWCS report (Barraj, L.M. et.al, 2004). Figure 7a depicts the total number of occasions that survey respondents reported consuming (direct) drinking water throughout the day. The ~~high numbers~~ data support the expectation that drinking water is consumed throughout the day, and that an eating occasion analyses may be useful in refining a dietary risk assessment for aldicarb.

Figure 7a Total Number of Occasions of Direct Drinking Water Consumption

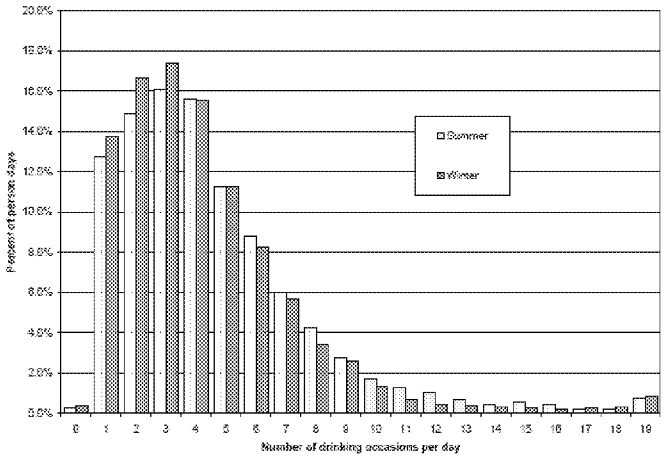


Figure 7b Distribution of Direct Drinking Water Consumption, By Time of Day

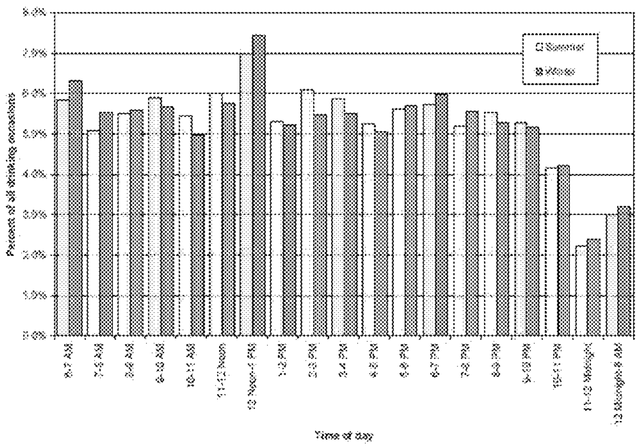


Figure 7b indicates that individuals consume drinking water at all times during the day. While this chart may lend support to the modeling assumption used for direct drinking water (6 equally fixed times), it is not directly applicable since this distribution applies to the entire population, and not to any particular individual.

c Sensitivity Analyses on Direct Drinking Water Consumption (Bayer data)

Table 10 Total Number of Diaries in Bayer DWCS

Total Number of DWCS Diaries, By Age-Gender-Season				
Age Bin	Gender	Season		Total
		Winter	Summer	
1 yr	Male	98	128	226
	Female	136	29	165
	Total	234	157	391
2 yrs	Male	167	97	264
	Female	125	73	198
	Total	292	170	462
3 yrs	Male	132	81	213
	Female	151	89	240
	Total	283	170	453
4 yrs	Male	128	63	191
	Female	149	98	247
	Total	277	161	438
5 yrs	Male	141	109	250
	Female	67	63	130
	Total	208	172	380
6-12 yrs	Male	663	404	1,067
	Female	624	457	1,081
	Total	1,287	861	2,148
13-19 yrs	Male	491	322	813
	Female	577	368	945
	Total	1,068	690	1,758
20-49 yrs	Male	2,871	1,999	4,870
	Female	4,036	2,544	6,580
	Total	6,907	4,543	11,450
50+ yrs	Male	1,975	1,688	3,663
	Female	3,332	2,717	6,049
	Total	5,307	4,405	9,712
Grand Total	Males	6,666	4,891	11,557
	Females	9,197	6,438	15,635
	Total	15,863	11,329	27,192

Table 10 indicates the total number of drinking water diaries in the DWCS by gender, age and season. This provideds us with an alternative approach to allocating direct drinking water consumption, rather than the six equally fixed occasions noted above. The procedure used to incorporate these data were:

- Generate cohort by gender, age, season (36 bins in Table 10)
- Calculate percentage of direct DW by each E.O.
- Merge total DW from CSFII with Bayer DW data
- Use Total DW from CSFII and percentage of DW from Bayer DW data to calculate DW amount for each O.E. (occ_time from Bayer data)
- There is no data for infant to implement option C

Table 11 compares the results of this alternative allocation of direct drinking water consumption with the six equally fixed approach. For infants, the results are the same since there were no infant diaries in the DWCS [DJM note: it is not clear to me how, if there are no surveyed infants in the Bayer DWCS survey how we end up with "the same" answers] ; but as noted above, it is indirect drinking water which contributes to exposures for this infant subpopulation. As the two estimates indicate, the risks at the per capita 99.9th percentile appears to be relatively robust with respect to the allocation of direct drinking water consumption over the day.

Table 10. SHEDS Estimated EO Risk at Per Capita 99.9th Percentile

2 hr Half-Life, Direct DW Consumption: Baseline=6 fixed events					
	Risk (%aPAD) at the Per Capita 99.9th%				
Subpopulation	**Food Only**	**GA-GW 300 ft**	**GA-GW 500 ft**	**GA-GW 1000 ft**	**FL-SW 1000 ft**
US Population	35%	55%	42%	36%	41%
Infants	41%	139%	85%	42%	77%
1-2 yrs	77%	91%	80%	78%	79%
3-5 yrs	57%	71%	61%	57%	60%
6-12 yrs	43%	46%	44%	43%	44%
13-19 yrs	31%	44%	34%	31%	33%
20-49 yrs	30%	52%	37%	30%	36%
50Plus	32%	45%	36%	33%	35%
Females 13-49 yrs	30%	50%	37%	30%	36%
2 hr Half-Life, Direct DW Consumption: Bayer DWCS					
	Risk (%aPAD) at the Per Capita 99.9th%				
Subpopulation	**Food Only**	**GA-GW 300 ft**	**GA-GW 500 ft**	**GA-GW 1000 ft**	**FL-SW 1000 ft**
US Population	35%	66%	46%	36%	44%
Infants	41%	139%	82%	42%	78%
1-2 yrs	77%	100%	81%	78%	80%
3-5 yrs	57%	101%	72%	58%	71%
6-12 yrs	43%	62%	46%	44%	45%
13-19 yrs	31%	53%	37%	31%	36%
20-49 yrs	30%	64%	43%	30%	41%
50Plus	32%	46%	36%	33%	35%
Females 13-49 yrs	30%	55%	39%	30%	37%

V. Risk Characterization & Summary

~~In t~~This memorandum ~~we have~~ summarizes ~~d~~ OPP's ~~our~~ dietary exposure modeling for aldicarb eating occasions using both the DEEM-FCID and the SHEDS-NMC models.

- Like DEEM-FCID, SHEDS-NMC was designed to utilize the CSFII two day diaries as its primary reference population; this leads to the similar results between the two models

- We can use the DEEM outputs (along with data from the USDA CSFII food diaries) to compute an Eating Occasion-based estimate; while this approach has a few limitations relative to SHEDS-NMC, it produces reasonably accurate results.

- The estimated risks under an eating occasions approach which incorporates decay rates are ~~may~~ be significantly lower than the total daily approach to the extent that exposures, in particular, drinking water exposures occur throughout the day (rather than during one instantaneous event).

- ~~Preliminary sensitivity analyses conducted on the half-life indicates that exposure and risks at the per capita 99.9th percentile is fairly robusts to reasonably small changes in this parameter~~

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- ~~High i~~Infants exposures relative to exposures to other subpopulations are exclusively due to their higher rates of drinking water consumption

- A few infant food diaries may be outliers ***[note from DJM: let's rephrase this]***; but our preliminary sensitivity analyses indicates that the estimated risks at the per capita 99.9th percentile are~~is~~ relatively robust~~s~~ to these diaries: specifically, ~~-~~ discarding~~ropping~~ these diaries, or reducing the amounts consumed by fifty percent, has only small effects upon the estimated risks.

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- The CSFII did not collect information on the timing of Direct Drinking Water intake. Any allocation of this total amount, as reported by the CSFII respondents, needs to be modeled either by a simple example (e.g., 6 equally fixed times), or by use of survey data.

- We empirically utilized the Bayer sponsored DWCS data to produce an alternative method for allocating drinking water intake throughout the day. The corresponding exposures and risks at the per capita 99.9th percentile did not change relative to the simple assumption that was initially utilized.